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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,715	03/04/2005	Stefan Golz	Le A 35 949	3124

35969 7590 06/13/2006

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EXAMINER	
SHAFER, SHULAMITH H	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,715	GOLZ ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims

The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Shulamith H. Shafer, Art Unit 1647.

Applicant's election Group II, claims 2-11, and species B, cardiovascular diseases, drawn to a methods of screening for therapeutic agents, in the reply filed on 13 April 2006 in response to the 15 March 2006 Office Action is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Upon further consideration, the restriction between Groups I and II is removed and Group II is rejoined with Group I. The restriction between these two groups and groups III-X, remains.

Claims 1-26 are pending in the instant application. Claims 12-26 are withdrawn from consideration as being drawn to non-elected invention. Claims 1-11 are under examination to the extent they read on elected invention.

Objections

Drawings/Figures

Figures 1-5 are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Appropriate correction is required. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein

sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Claims:

Claims 1-3 are objected to as encompassing non-elected inventions. Appropriate correction is required.

Claim 3 is objected to because of the following informalities: Claim 3, part ii recites "polypeptide at the presence of a compound". Appropriate correction is required so that claim is grammatically correct.

Claim Rejections

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are incomplete method claims. To be complete, a method claim must state a goal in the preamble of the claim, and conclude having achieved that goal. The preamble to each of these claims recites "a method of screening for therapeutic agents" but the method steps as recited are insufficient to accomplish the goal stated in the preamble. While all of the technical details of a method need not be recited, the claims

should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

Furthermore, Claims 1-3 identify the polypeptide of interest as FPRL-1. The polypeptide should be identified in full as N-formyl peptide receptor like-1 the first time it is recited in the claims.

Additionally, Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step comparing the activity determined in step i to that in step ii and a correlation step describing how the results of the assay allow for the determination.

Claim 4 recites the limitation "the method of any of claims 1 to 3 wherein the step of contacting is in or at the surface of a cell ". There is insufficient antecedent basis for this limitation in the claim since claims 2 and 3 do not recite "the step of contacting".

Claim 5 recites the limitation "the method of any of claims 1 to 3 wherein the cell is in vitro". There is insufficient antecedent basis for this limitation in the claim since claims 1-3 do not recite "the cell".

Claim 6 recites the limitation "the method of any of claims 1 to 3 wherein the step of contacting is in a cell-free system". There is insufficient antecedent basis for this limitation in the claim since claims 2 and 3 do not recite ""the step of contacting".

Claim 8 is indefinite in that it recites "wherein the compound is coupled to a detectable label". Claim 3 recites "a test compound" (step i) and a "compound". It is unclear which compound applicants intend to couple to a detectable label.

Claim 9 is indefinite in that it recites "wherein test compound displaces a ligand which is first bound to the polypeptide". It is unclear at which step in the methods of claims 1-3 the displacement step is to be undertaken.

Claim 11 is indefinite in that it recites "wherein the compound is attached to a solid support". Claim 3 recites "a test compound" (step i) and a "compound". It is unclear which compound applicants intend to attach to a solid support.

Claims 7 and 10 are included in this rejection as being dependent from rejected claims.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The instant invention encompasses a method of screening for therapeutic agents useful in the treatment of cardiovascular diseases comprising contacting a test compound with a FPRL1 polypeptide and detecting binding of said test compound to said FPRL1 polypeptide (method of Claim 1), determining the activity of a FPRL1 polypeptide at different concentrations of a test compound (method of Claim 2) or

determining the activity of a FPRL1 polypeptide at a given concentration of a test compound and determining the activity of a FPRL1 polypeptide in the presence of a compound known to be a regulator of a FPRL1 polypeptide (method of claim 3).

The instant invention is not considered to be enabled for the following reasons. Applicants have not established a nexus between an FPRL1 polypeptide and cardiovascular diseases in general and/or a specific cardiovascular disease. The specification and/or the art fail to establish a connection between FPRL1 structure, expression or activity or changes in structure, expression or activity and any specific cardiovascular disease condition or pathology. The specification teaches that FPRL1 is a receptor for N-formyl-peptides; the expression of the receptor in phagocytes and neutrophils has been described (page 4, lines 16-17). Applicants teach that "cardiovascular diseases include but are not limited to disorders of the heart and vascular system like congestive heart failure, myocardial infarction, ischemic diseases of the heart, all kinds of atrial and ventricular arrhythmias, hypertensive vascular diseases, peripheral vascular diseases and atherosclerosis" (page 57, lines 5-10). The art recognizes that all of these cardiovascular diseases are complex, multifactorial syndromes. While inflammation may play a role in the etiology or progression of some or all of the diseases, there is no art-established nexus between changes in FPRL-1 protein expression or activity and cardiovascular pathologies. Le et al. (2002, Trends in Immunology 23:541-548) teach that the FPRL-1 receptor, known to be involved in host defense against bacterial infection, has also been found to interact with a menagerie of structurally diverse ligands associated with diseases such as amyloidosis, Alzheimer's disease, prion disease and HIV (abstract). However, the art does not support a role for changes in FPRL1 protein activity or expression in cardiovascular diseases.

The specification teaches FPRL1 is highly expressed in different cardiovascular related tissues and asserts that expression in the tissues of the cardiovascular system suggests an association between FPRL1 and cardiovascular diseases (page 57, lines 10-14). However, the working example, which gives the results of the mRNA-quantification (expression profiling), indicates that FPRL1 mRNA is expressed in a wide

variety of organs and tissues and not specifically expressed in organs of the cardiovascular system. Moreover, it is difficult to interpret the data presented in Table 1 (page 85), since relative expression in left ventricle of the heart is 2048, expression in the right atrium is 1652, in the left atrium is 1342, while expression in the heart is 241. There is no data disclosing what, if any, changes in expression of FPRL1 mRNA accompany any diseased states, much less cardiovascular disease. Furthermore, the art recognizes that expression of DNA or RNA, does not always correlate with polypeptide levels (1998, Haynes et al. Electrophoresis 19:1862-1871). Haynes et al studied more than 80 proteins with relatively homogeneous half lives and expression levels and found no strong correlation between protein and transcript level. For some genes, equivalent mRNA levels translated into protein levels that varied more than 50-fold. Haynes et al. concluded that the protein levels cannot be accurately predicted form the level of the corresponding mRNA transcript (page 1863, 2nd paragraph and Figure 1). Anderson et al. (1997, Electrophoresis 18:533-537) teaches that the mRNA-protein correlation is poor in human tissue, an indication that "post-transcriptional regulation of gene expression is a frequent phenomenon in higher organisms" (page 533, abstract).

By failing to provide any evidence or working examples of a connection between FPRL1 and cardiovascular disease or any disclosure of cardiovascular conditions associated with altered levels (increase or decrease) of said polypeptide, applicant fails to provide any guidance as to which disorders would be treated by agents identified by the methods of the instant invention. Clearly, undue experimentation would be required to ascertain the function of FPLR1 in cardiovascular system, and to identify a disease with which this protein is associated. Additionally, the claims are drawn to a method of screening for therapeutic agents utilizing a FPRL1 polypeptide and determining binding of test compound to said polypeptide or determining the activity of FPRL1 polypeptide in the presence or absence of a test compound. Neither the FPRL1 peptide nor the activity of said peptide is further defined in the recited claims. The specification asserts that a FPRL1 polypeptide, within the meaning of the invention, shall be understood as being a polypeptide consisting or comprising polypeptides of SEQ ID

NO:2, polypeptides encoded by FPRL1 polynucleotides and/or polypeptides which show at least 99%, 98%, 95%, 90% or 80% homology with any polypeptides referred to above, wherein said polypeptide has FPRL1 activity (page 9, lines 1-13). Activity is not specifically defined in the specification, but refers to "biological and/or antigenic activity of a FPRL1 polypeptide" (page 6, lines 24-26).

The specification and working examples are all directed to a full-length protein of SEQ ID NO:2, encoded by a nucleotide sequence, accessible in public databases by accession number NM_001462, and given in the specification as SEQ ID NO:1. There is insufficient guidance in the specification as to which portion of the FPRL1 polypeptide must be retained in order to maintain the biological activity of the receptor.

The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein with the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequences are critical to the protein's structure/function relationship, such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (Wells, 1990, *Biochemistry* 29:8509-8517; Ngo et al., 1994, *The Protein Folding Problem and Tertiary Structure Prediction*, Merz et al., eds, Birkhauser, Boston, pp. 491-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active protein variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further

experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity.
Furthermore, the specification does not teach which of the many biological activities associated with activation of the FPRL1 receptor would be assessed in the methods of the instant invention. Le et al. (cited above) teach that these receptors mediate trafficking of phagocytes to site of bacterial invasion or tissue damage in response to pro-inflammatory ligands (page 541, 1st column); however the receptors also mediate anti-inflammatory action *in vivo* and may act by cross-desensitizing receptors for other chemoattractants and chemokines (page 541, 2nd column, 1st paragraph). One would have to undertake undue experimentation to first establish a nexus between FPRL1 polypeptides and cardiovascular disease, identify which biological activity of FPRL1 could be associated with cardiovascular disease and determine which of the variants of the protein recited above would retain the biological activity of the FPRL1 polypeptide in order to practice the methods of the claimed invention.

Due to the large quantity of experimentation necessary to determine a nexus between FPRL1 and cardiovascular disease, and to generate the infinite number of derivatives recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that activation of FPRL1 results in a wide variety of biological activities, and the breadth of the claims which fail to recite particular biological activities and also embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of screening for therapeutic agents using FPRL1 polypeptides (SEQ ID NO:2), encompassing polypeptides which show at least 80%, 90%, 95% or 99% sequence identity with SEQ ID NO:2. The claims do not require that the polypeptide possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity to SEQ ID NO:2. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the

method of isolation. Adequate written description requires more that a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an FPRL1 comprising the amino acid sequence set forth in SEQ ID NO:2, encoded by a nucleotide sequence, accessible in public databases by accession number NM_001462, and given in the specification as SEQ ID NO:1, but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 35 U.S.C. 112 is severable from its enablement provision (see page 115).

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fiore et al (1994, J Exp Med. 180:253-260). The claims are drawn to a method of screening for therapeutic agents useful for treatment of cardiovascular diseases comprising detection of binding to FPRL1 polypeptide (Claim 1), determining the activity of a FPRL1 polypeptide at different concentrations of a test compound (Claim 2) or determining the activity of FPRL1 at a known concentration of test compound compared

to activity in presence of "regulator of FPRL1 polypeptide" (Claim 3). The claims recite the further limitation of contact is at cell surface (Claim 4), wherein cell is *in vitro* (Claim 5), wherein the contacting is in a cell-free system (Claim 6), wherein the compound is coupled to a detectable label (Claim 8), wherein the compound displaces a ligand which is first bound to the polypeptide (Claim 9), wherein the polypeptide is attached to a solid support system (claim 10).

"Method of screening for therapeutic agents useful in treatment of a disease consisting of cardiovascular disease" is a recitation of intended use in the preamble of Claims 1-3. Applicants have recited incomplete method steps and have not disclosed any nexus between changes in FPRL1 structure, expression or activity and any cardiovascular disease. Therefore, the recited preamble is not given patentable weight. The methods recite the steps of contacting a FPRL1 polypeptide with a test compound and detecting binding to or determining activity of a FPRL1 polypeptide.

Fiore et al. teach identification of a high affinity LXA4 receptor protein (identified as FPRL1 in the instant invention). They teach expression of the receptor in Chinese hamster ovary cells (CHO) grown in petri dishes (page 254, 1st column, last paragraph) and measure the binding of [^{3}H]LXA4 (labeled ligand or test compound) to intact cell suspensions and subcellular fractions (page 254, 2nd column, 1st paragraph), thus anticipating the limitations of claims 1, 2, 4-6, 8, and 10. Fiore et al teach eicosanoid competition of [^{3}H]LXA4 binding, utilizing different concentrations of test eicosanoid compounds (page 256, table 1), thereby anticipating the limitations of claims 3 and 9. Thus the teachings of Fiore et al. anticipate all the limitations of claims 1-6 and 8-10.

Claims 1 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Seo et al (1997, J Immunology 158:1895-1901).

Seo et al teach binding of a peptide which binds to FPRL1 receptor to U266 cells. The U266 cells are bound to the immobilized peptide (page 898, figure 3). The ligands are bound to BIAcore sensor chip CM5 (page 396, 2nd column, 1st paragraph). Thus, the teachings of Seo et al anticipate the limitations of claims 1 and 11.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore et al (1994, J Exp Med. 180:253-260) in view of Ramakrishnan (US PGPub 2002/0058259, filed 14 March 2001).

The teachings of Fiore et al. are outlined in detail above. Fiore et al. do not teach a method comprising contacting a test compound with a FPRL1 polypeptide and detecting binding of said test compound to said FPRL1 polypeptide wherein said polypeptide is coupled to a detectable label.

Ramakrishnan teaches binding assays comprising contacting a test compound with the binding site of a lipoxin A4 receptor-like polypeptide, a GPCR (paragraph 0149). The reference teaches that in binding assays, either the test compound or the lipoxin A4 receptor-like polypeptide can comprise a detectable label (paragraph 0150).

The art teaches that FPLR-1 polypeptides, identified as GPCRs, bind LXA4, and could thus be defined as lipoxin A4 receptor-like polypeptides.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the methods of Fiore et al and modify these methods to utilize a receptor polypeptide comprising a detectable label as taught by Ramakrishnan. The person of ordinary skill in the art would have been motivated to make that modification because Ramakrishnan teaches that in binding assays, either the test compound or the lipoxin A4 receptor-like polypeptide can comprise a detectable label. One would have expected success because methods of making recombinant proteins comprising detectable labels are well known in the art and disclosed by Ramakrishnan (see for example, paragraphs 104 and 105).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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